UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: KIND LLC "HEALTHY AND ALL NATURAL" LITIGATION	ECF Case
	Case No. 1:15-md-02645-WHP
THIS DOCUMENT RELATES TO: ALL ACTIONS	**DEFENDANTS KIND LLC AND KIND MANAGEMENT, INC.'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO LIFT STAY**

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I. INTRODUCTION

On September 28, 2016, the Court stayed plaintiffs' "natural" claims under the primary jurisdiction doctrine in deference to FDA action regarding regulating the use of the term "natural" in food labeling. *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 697 (S.D.N.Y. 2016) (hereinafter "*KIND*").[1] As to plaintiffs' request to lift the stay, KIND understands that the Court is interested in: (i) the status of FDA's rulemaking on "natural"; (ii) what, if any, impact President Trump's administration will have on this rulemaking; and (iii) whether a continued stay will prejudice the parties. KIND addresses each of these issues below. At the outset, however, it is important to underscore that there can be no dispute that ***the question of whether and how FDA will regulate "natural" claims remains under formal consideration by FDA***. It has been only a little over one year since FDA closed its comment period on the use of the term "natural." In light of the fact that FDA received over 7,000 comments, and must review, consider, and exercise its judgment as to those comments to create a coherent national policy, it is not surprising that FDA's action with respect to "natural" remains ongoing and is not yet complete. Significantly, other than plaintiffs' counsel's say-so, there is no basis for any conclusion other than that FDA currently intends to provide clarity and uniformity to consumers and food manufacturers alike, and is working toward that goal.

[1] In its September 15, 2016 Order, this Court memorialized its careful consideration and balancing of the primary jurisdiction factors set forth in *Ellis v. Tribune Television Co.*, 443 F.3d 71, 82 -83 (2d Cir. 2006) and ruled that the factors supported a stay. *KIND*, 209 F. Supp. 3d at 696 ("staying this action until the FDA offers guidance at the federal level would almost certainly help harmonize court rulings—an important consideration [. . .] in order to avoid the need for '[m]anufacturers . . . to print 50 different labels.'") (citation omitted). The Court further emphasized that a decision from FDA regarding use of the term "natural" would shed light on issues central to this case, including "whether ingredients such as soy protein isolate and citrus pectin should be considered 'natural.'" *Id.* at 696. None of these facts relevant to the *Ellis* factors has changed since that time, and, accordingly, they continue to balance in favor of a stay.

Setting aside their attempted re-litigation of the *Ellis* factors, plaintiffs' request to lift the stay really comes down to an argument that FDA is taking too long. But that argument fails for two threshold reasons. As an initial matter, the time FDA needs to complete its work is not a determinative factor under *Ellis* (*see KIND*, 209 F. Supp. 3d at 696), especially where, as here, the labels no longer bear the challenged statements and plaintiffs are already enjoying a best-case-scenario result (*see* pp. 13-14, *infra*). Moreover, plaintiffs' assertion that "FDA has done absolutely nothing regarding promulgation of any such rule" (Mot. at 1) during this period is entirely speculative and is contradicted by the relevant facts. Plaintiffs have no idea what FDA is doing on a day-to-day basis, the state of its staffing, the state of its budget or, significantly, how any of that impacts FDA's work on regulating the word "natural." Nevertheless, plaintiffs surmise—with citation to nothing—that FDA has budget and staffing shortages that will uniquely affect FDA's ability to develop a rule relating to "natural" labeling. Similarly, plaintiffs' citation to an executive order that generally addresses, though does not bar, the issuance of certain new regulations is entirely insufficient. The executive order does not address, let alone curtail, regulating the word "natural."

In contrast to plaintiffs' unsubstantiated speculation or complaints about mere delay, the indisputable facts are that FDA (i) made absolutely clear that it intends to look at regulating use of the word "natural" on food labels (80 Fed. Reg. 69905, 69905 (Nov. 12, 2015)), (ii) has now received more than 7,000 comments, and (iii) necessarily needs time to consider, assess and resolve the many technical and policy issues involved. What is more, Congress is currently in the process of asking FDA for a status update on its "natural" work. *Infra*, page 4.

On this record, plaintiffs have not moved the needle on any of the *Ellis* factors, or offered a coherent justification as to why they should get to litigate technical and policy issues

of "natural" food labeling when FDA is currently considering the same issues to arrive at a national policy. For these, and several other reasons detailed below, KIND respectfully asks that plaintiffs' motion be denied and the stay be kept in place until FDA completes its work on regulating the use of the word "natural" on food labels.

II. ARGUMENT

A. FDA Is The Appropriate Agency To Consider A "Natural" Definition And The Stay Should Remain While FDA Continues Its Work

The propriety of awaiting FDA action on the definition of "natural" has been recently confirmed by Congress' express acknowledgment that FDA can and should promulgate a national standard for the use of "natural" in food labeling. Specifically, the July 17, 2017 bill report accompanying the 2018 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill provides:

> Natural Definition.—The Committee commends the FDA for taking the first step towards defining the term ''natural'' and regulating its use on food labeling by requesting public comment on a number of relevant questions in a November 2015 Federal Register notice. The Committee directs FDA to provide a report within 60 days of enactment of this Act on the actions and timeframe for defining ''natural'' so that there is a uniform national standard for the labeling claims and consumers and food producers have certainty about the meaning of the term.

H.R. Rep. No. 115-232 (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2018), Title VI Related Agencies and Food and Drug Administration, p. 72.[2] This report not only demonstrates that Congress believes that FDA is the appropriate body to consider defining the term "natural" but, more importantly, that it expects FDA to complete its work and issue a final rule on the use of the term "natural" in food labeling. Contrary to plaintiffs' unsubstantiated and speculative assertions otherwise, the report is entirely consistent with the understanding that FDA will continue working to complete its evaluation of the use of the term "natural" on food labeling. That, in turn, supports maintaining the stay. Additionally, if the Appropriations Bill is passed, FDA will be directed to report to Congress on the status of "natural" rulemaking ***within 60 days*** of enactment of the Act. *Id.* Accordingly, plaintiffs' claims that FDA is not acting will—following that 60 day period—

[2] Available at https://www.congress.gov/115/crpt/hrpt232/CRPT-115hrpt232.pdf.

either be confirmed or not by FDA. Waiting a mere 60 days after enactment of the Act can provide additional certainty on FDA's intentions and activities—a fact which militates in favor of keeping the stay in place until at least that time.

B. The Current "Wait Time" For FDA Action on "Natural" Labeling Is Well Within The Time FDA Typically Takes To Act

The time period during which FDA has been considering "natural" labeling rules is well within what is expected based on historical timeframes for FDA to promulgate guidance and rules. Given its nature—poring over industry and public comments to answer difficult technical and policy questions—agency work is necessarily time consuming. A period of two to five years is an expected and reasonable amount of time for a regulatory agency to complete its important work and promulgate a rule. *See Kelley v. WWF Operating Co.*, 2017 WL 2445836, at *7 (E.D. Cal. June 6, 2017) ("[a]gency decisionmaking often takes a long time" and agencies can take two to five years) (internal quotations and citations omitted); *see also Canale v. Colgate-Palmolive Co.*, -- F. Supp. 3d --, 2017 WL 2729493, at *9 (S.D.N.Y. June 23, 2017) (initial *issuance* of a stay pursuant to primary jurisdiction is appropriate *more than two years after* agency begins addressing issue implicated in case). Plaintiffs themselves refer to the "Reg Map" (Mot. at 9), which, along with other portions of the record in this case, merely confirms the well-known fact that regulatory agencies like FDA require time to consider technical and policy issues and promulgate new regulations. Rather than supporting lifting of the stay, plaintiffs' arguments only go to show that the time being taken by FDA to complete its work on "natural" was anticipated, and is well within a reasonable timeframe for a regulatory agency.

Indeed, it is not uncommon for cases, including food false advertising cases, to remain stayed for more than two years pending FDA action. For example, it took a little over two years from the time FDA re-opened the comment period on the use of the ingredient name

"evaporated cane juice" (March 5, 2014) the issuance of its final guidance (May 25, 2016). During that time, many cases remained stayed pursuant to the primary-jurisdiction doctrine. *See, e.g.*, *Figy v. Amy's Kitchen, Inc.*, Case No. 3:13-cv-03816 (N.D. Cal. Aug. 13, 2013) (remaining stayed until its voluntary dismissal on October 21, 2016); *Swearingen v. Late July Snacks LLC*, Case No. 3:13-cv-04324 (N.D. Cal. Sept. 18, 2013) (remaining stayed until July 2016); *Swearingen v. Healthy Beverage LLC*, Case No. 3:13-cv-04385 (N.D. Cal. Sept. 20, 2013) (same); *Gitson v. Clover-Stornetta Farms, Inc.*, Case No. 3:13-cv-01517 (N.D. Cal. Apr. 4, 2013) (remaining stayed until August 2016).[3]

Similarly, FDA has issued many *advanced* notices of proposed rulemaking years before issuing a notice of proposed rulemaking. In 2010, FDA issued an advance notice of proposed rulemaking regarding revision of nutrition facts labels and the prominence of calorie information (75 Fed. Reg. 39026 (July 7, 2010)), but it was not until 2014 that FDA issued its proposed rule on this issue. 79 Fed. Reg. 11880 (Mar. 3, 2014). Given the track record of regulatory activity at FDA, it is to be expected—under the usual course of action—that FDA has not yet promulgated a "natural" labeling rule or guidelines, and it is worth repeating that FDA does not keep citizens apprised of its precise activity along the way.

The Court understood when it stayed this case pursuant to FDA's primary jurisdiction that regulations are often promulgated over a period of two or more years, which is no less relevant today than it was when the Court first stayed plaintiffs' "natural" claims. We remain

[3] Plaintiffs themselves point to the ECJ cases as evidence that under even the prior regulatory regimes, "it took more than six-and-a-half years for the FDA to publish final guidance regarding use of the term 'evaporated cane juice' after it first published draft guidance on the subject." Mot. at 9. But the many ECJ cases stayed on primary jurisdiction grounds serve only to show that courts are willing to stay these types of cases in deference to FDA—even when FDA's rulemaking takes longer than parties had likely hoped.

well within the expected time for FDA to act concerning "natural," and plaintiffs provide no reason to believe FDA will not do so within the historically expected timeframe.

Significantly, the length of time that FDA takes to complete its deliberative process is not, in and of itself, a determinative factor. Indeed, "the Second Circuit has cautioned against weighing [potential delay] too heavily in view of the fact that 'the Supreme Court has consistently held that there are only two purposes to consider in determining whether to apply the primary jurisdiction doctrine—uniformity and expertise,' and 'the Supreme Court has never identified judicial economy as a relevant factor.'" *KIND*, 209 F. Supp. 3d at 696. Continuing the stay until FDA completes its work inures to the benefit of the Court and the parties because it will allow FDA to provide guidance on a technical area that its within is particular expertise and that needs a national—not patchwork, case-by-case—policy.

C. The Vast Majority Of Courts Considering This Issue Find That Continuing A Stay Pursuant To The Primary Jurisdiction Doctrine Is Appropriate

The value in allowing FDA to continue its work to establish a national, coherent, and uniform standard for "natural" has been overwhelmingly recognized—including quite recently—by the courts that have taken up the issue of staying litigation in deference to the FDA's primary jurisdiction, most in the face of spirited opposition complaining about the length of time it is taking FDA to complete its work. *See Scholder v. Riviana Foods Inc.*, 2017 WL 2773586, at *4 (E.D.N.Y. June 23, 2017) (staying case to allow FDA to engage in the 'natural' rulemaking process); *Scholder v. Sioux Honey Association Cooperative*, Case No. 2:16cv5369 (E.D.N.Y. June 27, 2017) (same); *In re General Mills, Inc. Kix Cereal Litig.*, Case No. 2:12-cv-00249, at ECF No. 209 (D.N.J. Apr. 21, 2017) (extending stay until 10/10/2017); *Forsher v. The J.M. Smucker Co.*, Case No. 1:15-cv-7180 (E.D.N.Y. Mar. 24, 2017) (denying request to lift existing stay); *see also Wong v. Newman's Own, Inc.*, Case No. 1:16-cv-06690, at ECF No.

29 (E.D.N.Y. Apr. 7, 2017); *Perera v. Pacific Foods of Oregon Inc.*, Case No. 3:14-cv-02047, at ECF No. 67 (N.D. Cal. Mar. 20, 2017); *Quiñones-Gonzalez v. Kraft Foods Group. Inc*, Case No. 3:15-cv-1892, at ECF No. 36 (D.P.R. Mar. 3, 2017); *Thornton v. Pinnacle Foods Group, LLC*, 2016 WL 5793193, at *2 (E.D. Mo.Sept. 30, 2016); *Kane v. Chobani*, Case No. 5:12-cv-02425, at ECF No. 182 (N.D. Cal. July 29, 2016); *Mains v. Whole Foods Market, Inc.*, 2016 WL 5791414, at n.2 (N.D. Cal. Apr. 18, 2016); *Anderson v. The Hain Celestial Group, Inc.*, Case No. 5:14-cv-03895, at ECF No. 62 (N.D. Cal. Apr. 8, 2016); *Smedt v. The Hain Celestial Group, Inc*., Case No. 5:12-cv-03029, at ECF No. 97 (N.D. Cal. Apr. 7, 2016); *Samet v. Proctor and Gamble Company*, Case No. 3:12-cv-01891, at ECF No. 177 (N.D. Cal. Apr. 4, 2016).

In contrast to this avalanche of authority, plaintiffs identify two cases in support of their argument that the decisions of other courts counsel in favor of lifting the stay here. Mot. at 4. And even these two cases are not helpful to plaintiffs because the underlying facts and the court's reasoning are completely distinguishable from this case.[4] In fact, one court considering this issue recognized that the cases cited by plaintiffs do not show that a "fundamental" change in tide has occurred, thereby justifying lifting a stay while FDA continues its work. *See In re*

[4] For example, in *In re Hain Celestial Seasonings Prods. Consumer Litig.*, Case No. 8:13-cv-1757 (C.D. Cal.), at ECF Nos. 315-17, Judge Guilford expressly recognized that his decision to lift the stay is an outlier, with the weight of authority militating towards a stay. *See* ECF No. 91-2 (herein), at 9 (transcript of November 7, 2016 proceedings). Moreover, at the time of the stay in *In re Hain Celestial*, the case had already proceeded through discovery and a motion for summary judgment had been fully briefed and heard. By lifting the stay, the court was able to rule on defendant's previously filed motion for partial summary judgment as to plaintiffs' injunctive relief claims. The court granted defendant's motion for reasons unrelated to what "natural" means, disposing of the case on a class-wide basis without the need for input from FDA on the definition of "natural." *See In re Hain Celestial*, at ECF No. 350 at p. 7. Similarly, in *Martin v. Tradewinds Beverage Co.*, 2017 WL 1712533, at *4 (C.D. Cal. Apr. 27, 2017), the court decided against granting a stay because "[t]he food labeling at issue here involves the addition of caramel food coloring, and [. . .] there is no representation from the FDA that resolution of the question of color additives is forthcoming." *Id.* Accordingly, unlike here, the *Tradewinds* court determined that FDA's work on "natural" food labeling would have no impact on the merits of that case.

General Mills, Inc. Kix Cereal Litig., Case No. 2:12-cv-00249 (D.N.J.), at ECF No. 209 p.1. Accordingly, if the Court were to find decisions by other district courts to be persuasive, the overwhelming weight of these decisions favors continuing a stay.

D. Plaintiffs' Characterization of The Trump Administration and Its Impact On The Regulatory Landscape is Wholly Speculative

Plaintiffs' primary arguments in support of their contention that FDA is not working on "natural" issues and, thus, this case will be delayed indefinitely are (1) President Trump has issued an executive order requiring any new regulations be revenue-neutral and include repeal proposals for other regulations (the "two-for-one rule"), and (2) FDA staffing and funding have been slashed. Mot. at 4-6. But plaintiffs provide absolutely no evidence in support of the argument that President Trump's Executive Order 13771 would even apply to any future FDA rulemaking regarding "natural" labeling, much less that it will have any impact on FDA's on-going work on "natural."[5] In addition, plaintiffs' general (and inaccurate) speculation about staffing, budget, and executive orders leading to potential delay is not compelling evidence that FDA's work on "natural" has halted.[6]

[5] This is also confirmed by the fact that FDA cannot indefinitely delay "natural" rulemaking. FDA has received at least four citizens' petitions regarding the term "natural" (*see* 80 Fed. Reg. 69905, 69906-08 (Nov. 12, 2015)) pursuant to 21 C.F.R. § 10.30, which sets time limits by which FDA must respond to such petitions. FDA has some leeway on the timing of its response, but absent a response, FDA can be sued for unreasonable delay pursuant to 5 U.S.C. §§ 702 and 706(1).

[6] Staffing and budget issues arise every time there is a change in presidential administration. If a court must decline to defer to agencies' primary jurisdiction every time a new president is elected, then the doctrine would become meaningless, as stays would be automatically lifted on every inauguration day. Indeed, KIND is aware of no case (and plaintiffs cited none) where a primary jurisdiction stay was lifted or denied because of a change in administration – which is, after all, hardly unexpected in a multi-year rulemaking process.

1. Plaintiffs' Contention That Executive Order 13771 Would Apply To "Natural" Rulemaking Is Speculative And Unsupported

Plaintiffs' argument regarding the two-for-one rule is based on a misperception of the Executive Order's scope, which is in fact narrow. There are no facts or evidence that the Executive Order will in any way impact FDA's "natural" rulemaking. In fact, this argument has already been rejected by at least one court:

> [Executive Order No. 13771] is general. It requires that all new regulations be accompanied by proposals for repeal of other regulations, and that they be revenue-neutral. That is very far from an indication that the FDA intends to abandon its regulatory efforts as to the kind of 'natural' labeling claims involved in this action, or that the need for regulatory expertise has abated,

In re General Mills, Inc. Kix Cereal Litig., Case No. 2:12-cv-00249 (D.N.J.), at ECF No. 209 p.1 (continuing the stay).

Significantly, the "two-for-one" order is not an absolute bar to the promulgation of new rules. Instead, the executive order applies only in limited circumstances, *i.e.*, "significant regulatory actions," and merely seeks to add additional requirements that must be met for such significant regulatory action to be taken—not to prevent it entirely.[7] Thus, in order for the "two-for-one" order to apply to FDA's rulemaking surrounding the phrase "natural," FDA would have to determine its rulemaking falls into the category of a "significant regulatory action."[8] Although we do not yet know what the rule FDA intends to promulgate will look like,

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[7] Guidance Implementing Executive Order 13771, Titled "Reducing Regulation and Controlling Regulatory Costs," at 3. *See* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf.

[8] Executive Order 12866 defines a "significant regulatory action" as "any regulatory action that is likely to result in a rule that may: "(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of

it is highly unlikely that any proposed rule regarding "natural" food labeling will have an annual effect on the economy of $100 million or more (for example) and thus, it is improbable that the "two-for-one" order would even apply. Thus, the "two-for-one" order by no means implies that FDA's hands are tied, preventing it from developing a rule regarding "natural."

Finally, even if the "two-for-one" order would end up applying to any future "natural" regulation, that does not equate to a finding that such application would cause delay in FDA proposing a "natural" rule. Issuing a rule and implementing a final rule are two different things and nothing in the "two-for-one" order, in the unlikely event it would be applicable here, prevents FDA from issuing a rule on "natural" labeling. And to the extent FDA's future implementation of a final rule was relevant to this analysis (it is not), FDA could always propose two regulations to eliminate[9]; plaintiffs have proffered no specific evidence that compliance with the order is unlikely or impossible. There simply is no basis for plaintiffs' assertion that FDA is abandoning its regulatory responsibilities and is not moving forward with its duties. To the contrary, FDA is providing every indication that it continues to forge ahead with its regulatory responsibilities, as it is doing with menu labeling requirements.[10] Plaintiffs

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entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.

[9] The two proposed regulations to be eliminated do not need to be related to "natural" labeling and do not need to be identified at the same time as the proposed new regulation. Instead, guidance for implementation of the Executive Order provides that the balance of new to old regulations should be determined at the end of the fiscal year. *See Guidance Implementing Executive Order 13771, Titled "Reducing Regulation and Controlling Regulatory Costs," available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf* at pp. 14-16.

[10] *See* https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm (page updated May 4, 2017).

do not have a crystal ball, and cannot use a general order that applies only to certain agency action as a basis to claim that specific rulemaking surrounding "natural" will not occur or that will prohibit FDA from continuing its work on "natural" labeling. Plaintiffs' speculation—and incorrect analysis of the "two-for-one" order—does nothing to change the analysis that the Court undertook when the stay was put in place.

2. Plaintiffs' Contentions Regarding FDA Staffing And Budget Are Unsupported

Plaintiffs' argument that FDA is hampered by a hiring freeze and resource crunch (Mot. at 6) is unsubstantiated and speculative. Regarding staffing, plaintiffs provide no reason to believe that any perceived staffing shortages will uniquely affect FDA's ability to promulgate a regulation regarding "natural." What is more, Dr. Scott Gottlieb was sworn in as FDA Commissioner on May 11, 2017. In testimony to the Senate Appropriations Subcommittee in June 2017, he explained that FDA had negotiated the lifting of the hiring freeze plaintiffs cite, that FDA was moving forward to fill vacancies, and "there's already activity with filling some of those existing slots." *See* Declaration of Keri E. Borders, Ex. A, Tr. at 4.

Plaintiffs' contention that there is no budget to promulgate new rules (Mot. at 5-6) is likewise unsupported. Plaintiffs refer to the President's proposed budget, but this budget has not been approved by Congress and there is no evidence that the President's initial proposed budget will be the final budget that is ultimately approved by Congress.[11] The impact that the

[11] Historically, presidents' proposed budgets do not forecast the budget that will ultimately be approved, and there is reason to believe that this trend will not hold here as well. *See* Amber Phillips, "Congress Doesn't Want to Touch Trump's Budget with a 10-foot Pole," The Washington Post, May 23, 2017 (noting that presidents' budgets are "never really intended to be written straight into law"), available at https://www.washingtonpost.com/news/the-fix/wp/2017/05/23/congress-doesnt-want-to-touch-trumps-budget-with-a-10-foot-pole/?utm_term=.d4a2f66da3f3. Justin Bogie, "Trump's Budget is Good for America, So Why is Congress Ignoring It?," The Hill, July 11, 2017 (Congress is ignoring President Trump's budget, and "there is an increasing chance that Congress will look to pass a budget agreement in

President's proposed budget (or the actual, approved budget) will have on FDA is simply unknown at this time.

E. Plaintiffs' Argument That Any Potential Rulemaking By FDA On "Natural" Would Be Irrelevant To This Case Is Incorrect

This case was originally stayed in order to allow the Court and the parties to have the benefit of FDA's thinking and guidance on the definition of "natural." *KIND*, 209 F. Supp. 3d at 696. Plaintiffs' current argument that FDA rulemaking on "natural" labeling would be irrelevant because it will not be retroactive (Mot. at 8) is a re-hash of a prior argument that was already considered and not adopted by this Court and should be rejected now. A stay is appropriate—and should be continued—because FDA's rulemaking could be immediately applicable in this case (and any other pending cases) in numerous ways.[12] For instance, if FDA promulgates a regulation that falls within 21 U.S.C. § 343-1, it could provide KIND with an express preemption argument. Moreover, it is possible that—whatever FDA decides—will be accompanied by a compliance period or safe harbor that could provide an additional defense to KIND, including possibly conflict preemption. *See Backus v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068, 1072-73 (N.D. Cal. 2016) (allowing plaintiff's claims to proceed during a compliance

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September that follows in the fiscally irresponsible footsteps of a deal between President Obama and House Speaker John Boehner."), available at http://thehill.com/blogs/pundits-blog/economy-budget/341396-trumps-budget-is-good-for-the-country-so-why-wont-congress. *see also* Richard Manning, "Trump's Budget Really Could Make America Great Again. Will Congress Allow Him to do It?," Fox News Opinion, May 22, 2017 ("Most presidents' budgets are 'dead on arrival' in Congress," and stating that is what happened to Presidents Obama and Bush) Available at http://www.foxnews.com/opinion/2017/05/22/trump-s-budget-really-could-make-america-great-again-will-congress-allow-him-to-do-it.html.

[12] This is not retroactivity. This is the general principle that changes in the law apply to then-pending litigation. *See generally Fitzpatrick v. Tyson Foods, Inc.*, 2016 WL 5395955, at *4 (E.D. Cal. Sept. 27, 2016); *Rossetti v. Stearn's Prods., Inc.*, 2016 WL 3277295, at *4 (C.D. Cal. June 6, 2016); *Californians For Disability Rights v. Mervyn's, LLC*, 39 Cal. 4th 223, 233, 138 P.3d 207, 213 (2006). Such application does not require the new law to reach back in time.

period would conflict with Congress' intent that companies be given time to bring their products into compliance with the law).

The ultimate touchstone of plaintiffs' false advertising claims is whether consumers were actually deceived under state consumer protection law by KIND's label. While FDA regulations and guidance are ***not*** synonymous with consumer deception under state consumer protection laws, whatever FDA has to say about "natural" labeling will certainly be relevant to an inquiry in a then-pending case as to whether consumers would be deceived.[13] *See KIND*, 209 F. Supp. 3d at 696 ("Nevertheless, FDA guidance could explain whether ingredients such as soy protein isolate and citrus pectin should be considered 'natural.'").

F. Continuing The Stay Will Not Prejudice Plaintiffs

Plaintiffs' generic allegations of prejudice apply with equal force to any litigation and—absent specific facts to demonstrate that plaintiffs have in fact, or will be, harmed—are insufficient to support a lifting of the stay.

For starters, plaintiffs claim that consumers are prejudiced by "the harm that continues to befall" them. Mot. at 3. But this is both factually inaccurate and unnecessarily hyperbolic. KIND has removed the challenged "natural" statements from virtually all of its products' labels. *See* Declaration of Heather Sachs-Fromson at ¶ 3. Even assuming plaintiffs are correct and that the challenged "natural" labeling is deceptive (which it is not), consumers are protected from

[13] It is important to note that whatever FDA says would be, at best for plaintiffs, a starting point from which plaintiffs, in order to prevail, would have to further develop a record that consumers were actually deceived, under the state consumer protection laws which form the basis of their claims, by KIND's "natural" labeling statements.

any further injury because the "natural" label statement is no longer being disseminated to the public, making the length of time the stay remains in place is irrelevant.[14]

Plaintiffs next argue that leaving the stay in place would cause prejudice because evidence "grows stale, and witnesses' memories will fade." Mot. at 9. But these are nothing more than "usual litigation risks that affect all the parties equally." *Bethpage Water Dist. v. Northrop Grumman Corp.*, 2014 WL 6883529, at *3 (E.D.N.Y. Dec. 3, 2014). Moreover, plaintiffs have failed to provide "any specific examples of evidence that may become stale or witnesses whose memories may fade during the stay." *Id.* To the contrary, in cases involving stays concerning "natural" labeling, courts have determined that evidence likely to be relevant will be retained in the ordinary course of satisfying the discovery obligations of document preservation. *See Forsher v. J.M. Smucker Co.*, 2016 WL 5678567, at *3 (E.D.N.Y. Sept. 30, 2016); *Viggiano v. Johnson & Johnson*, 2016 WL 5110500, at *3 (N.D. Cal. June 21, 2016). Again, plaintiffs deal only in speculation and generalities, and provide no specific reasons for why witnesses or evidence in this case is likely to go stale. This generic and unsubstantiated "prejudice" is insufficient to justify lifting the stay.[15]

G. Lifting The Stay Will Prejudice KIND

In contrast to plaintiffs' generic allegations of prejudice, KIND is faced with serious and

[14] KIND's removal of the "natural" labeling statement also poses a hurdle to plaintiffs' ability to seek injunctive relief. *See In re Hain Celestial Seasonings Prod. Consumer Litig.*, Case No. 8:13-cv-1757 (C.D. Cal.), at ECF No. 350, at pp. 4-7; *Moroccanoil, Inc. v. Dermorganic Labs., Inc.*, 2009 WL 10675634, at *6 (C.D. Cal. Nov. 9, 2009). Accordingly, the only remaining relief sought by plaintiffs could be damages, for which delay is not inherently prejudicial.

[15] Moreover, this argument ignores the fact that KIND's impressions of and intent in using the term "natural" on its product labeling is irrelevant to plaintiffs' false advertising claims. It is only a reasonable consumer's understanding of what the term "natural" means that matters, not that of the company manufacturing the challenged products. *See In re 5-Hour Energy Mktg. & Sales Practices Litig.*, 2017 WL 2559615, at *7 (C.D. Cal. June 7, 2017). Any evidence concerning consumers' impressions of the term "natural" on the labeling is equally available to plaintiffs and may be preserved by them.

real prejudice if this action is allowed to move forward in advance of FDA's guidance on "natural." That is exactly why this Court previously recognized that "staying this action until the FDA offers guidance at the federal level would almost certainly help harmonize court rulings—an important consideration in view of the fact that 'Congress [did] not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide' in order to avoid the need for '[m]anufacturers ... to print 50 different labels.'" KIND, 209 F. Supp. 3d at 696 (internal citations omitted).[16] Moreover, allowing this case to move forward while FDA undertakes rulemaking will also prejudice KIND, as it is likely to result in the unnecessary expenditure of resources on costly discovery that may ultimately be rendered unnecessary. *See, e.g., Viggiano*, 2016 WL 5110500, at *3 ("[P]ermitting discovery while the FDA regulatory proceeding is underway may impose unnecessary burdens on Defendants by leading to discovery that could be rendered unnecessary by later FDA conclusions.").

H. The Stay Should Remain In Place While "GMO" Issues Are Stayed

KIND also moved for a stay of plaintiffs' "non-GMO" claims on primary jurisdiction grounds. ECF No. 101. Although the Court has not yet ruled on KIND's motion, if that motion is granted, all parties agree that there is no reason for the claims in this case to proceed piecemeal. ECF No. 103, 02/15/2017 Tr. at 21 ("it [doesn't] make[ ] sense for [the GMO]

[16] See *Coyle v. Hornell Brewing Co.*, 2010 WL 2539386, at *4 (D.N.J. June 15, 2010) ("Should this Court independently decide whether [the challenged ingredients are] natural ingredient[s], it is possible that other federal courts or the FDA will come to a different conclusion, resulting in inconsistent outcomes for essentially identical claims and affecting food and beverage purveyors with nationwide businesses." This "would impose a burden on this industry that may be alleviated if the FDA chooses to speak directly to the question."); *see also Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (Posner, J; preemption) (It is "easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products," as "[m]anufacturers might have to print 50 different labels . . . .")

claims to go forward necessarily while the natural claims are stayed[.]"). On that logic, the "natural" claims should not go forward while the "non-GMO" claims are stayed. This is especially true because plaintiffs' amended complaint *includes* "non-GMO" allegations as part of the "natural" claims. Compl. ¶¶ 48-49. The claims are so intertwined that this Court previously required plaintiffs to re-plead to indicate whether they intended to "assert a stand-alone 'non GMO' claim" at all. KIND, 209 F. Supp. 3d at 697.

USDA's GMO rulemaking is also likely to shed significant light on FDA's eventual definition of "natural." The FDA's opening of a "natural" docket expressly noted that FDA was "working with the United States Department of Agriculture (USDA) Agricultural Marketing Service and Food Safety Inspection Service to . . . examine the use of the term 'natural' in meat, poultry, and egg products," and that FDA was "considering areas for coordination between FDA and USDA," including in the context of deciding "whether food products containing ingredients produced used genetic engineering . . . may be labeled as 'natural.'" *Proposed Rules: Use of the Term 'Natural' in the Labeling of Human Food Products*, 80 Fed. Reg. 69905, 66905 (Nov. 12, 2015); *see also id*. at 69907 ("if we were inclined to revoke, amend, or revise our policy regarding use of the term 'natural,' we would likely engage in a public process and work with other federal entities, such as the U.S. Department of Agriculture"); Letter from Leslie Kux to Three Judges (Jan. 6, 2014), at 2, http://www.foodpolitics.com/wp-content/uploads/Letter-from-FDA-Declining-Intervention.pdf (defining the term 'natural' on food labeling necessarily involves interests of Federal agencies other than FDA, including the United States Department of Agriculture). Given this inter-relationship, the Court should be

reluctant to evaluate plaintiffs' claims before even one of the relevant agencies has had a chance to weigh in on the crucial issues.[17]

III. CONCLUSION

For the foregoing reasons, KIND respectfully requests that case remain stayed in deference to FDA's primary jurisdiction. If the Court opts to lift the stay, KIND respectfully requests the opportunity to update the briefing on its motion to dismiss the "natural" claims on grounds other than primary jurisdiction, including whether a reasonable consumer would be deceived in the manner alleged under *Pelayo v. Nestle USA, Inc.*, 989 F. Supp. 2d 973 (C.D. Cal. 2013) and others. *See* Mem. Of Law in Support re: Motion to Dismiss, ECF No. 66, at 16-24.

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Respectfully Submitted,

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[17] Since the parties submitted their briefing on whether or not to dismiss plaintiffs' GMO related claims, it is worth noting that USDA has now released 30 questions to interested stakeholders, whose input on these issues will be considered in USDA's rulemaking. *See* https://www.ams.usda.gov/rules-regulations/gmo-questions.